

PSJ3

Exhibit 469

## Message

**From:** Carol Kelly [CKelly@NACDS.org]  
**Sent:** 5/1/2012 9:07:39 AM  
**To:** Kevin Nicholson [KNicholson@NACDS.org]; Albert Garcia [albert.garcia@navarro.com]; Bob Egeland [begeland@hy-vee.com]; Christine Simmon [christine.simmon@cvscaremark.com]; Dan Salemi [daniel.salemi@supervalu.com]; Garza, Debbie [debbie.garza@walgreens.com]; Dennis Wiesner [wiesner.dennis@heb.com]; Fred Ottolino [fred.ottolino@publix.com]; John Carlo [john.carlo@wegmans.com]; Jonathan Thacker [jonathan.thacker@wakefern.com]; Karen Mankowski [karen.mankowski@meijer.com]; Kate Coler [kate.coler@safeway.com]; Kevin Connor [Kevin.Connor@McKesson.com]; Marc Baer [marc.baer@target.com]; Mark Gregory [mgregory@kerrdrug.com]; Mark Pilkington [mark.pilkington@cardinalhealth.com]; Mark Polli [mpolli@hannaford.com]; Michael Cantrell [MCantrell@amerisourcebergen.com]; Michael Hamilton [Michael.Hamilton@searshc.com]; Mike Podgurski [mpodgurski@riteaid.com]; Raymond McCall [raymond.mccall@aholdusa.com]; Rick Chambers [rchambers@fredsinc.com]; Susanne Hiland [susanne.hiland@wal-mart.com]; Hansen, Suzanne [suzanne.hansen@walgreens.com]; Sybil Richard [sybil.richard@wal-mart.com]; Tim Weber [tweber@fruthpharmacy.com]; Tim Weippert [tweippert@thriftywhite.com]; Tom Gibbons [TJGibbons@cvs.com]; Vic Curtis [vcurtis@costco.com]

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**Subject:** RE:Document for Policy Council Call - DEA Issues - Tuesday May 1 @ 1:15 p.m.  
**Attachments:** Drug Diversion - PDUFA.DOC

**Importance:** High

Please see attached a draft document that Kevin did for our 1:15 PM call today. I have been asked to send it to the full Executive Committee for a quick review directly after the 1:15 PM call so we look forward to your comments on it. The Health Subcommittee of House Energy and Commerce is set for PDUFA mark up next Tuesday so our window of opportunity on the House side is short for this.

All the best,

Carol

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**From:** Kevin Nicholson

**Sent:** Friday, April 27, 2012 3:48 PM

**To:** Albert Garcia; Bob Egeland; Christine Simmon; Dan Salemi; Debbie Garza; Dennis Wiesner; Fred Ottolino; John Carlo; Jonathan Thacker; Karen Mankowski; Kate Coler; Kevin Connor; Marc Baer; Mark Gregory; Mark Pilkington; Mark Polli; Michael Cantrell; Michael Hamilton; Mike Podgurski; Raymond McCall; Rick Chambers; Susanne Hiland; Suzanne Hansen; Sybil Richard; Tim Weber; Tim Weippert; Tom Gibbons; Vic Curtis

**Cc:** Alethia Jackson; Alex Adams; Allen Horne; Anika Hagenson; Anne Fellows; Ben Moscovitch; Beth Cieslik; Brad Dayton; Carol Kelly; Carolyn Steinberg; Charlie.Oltman; Chris Dimos; Chris Krese; Chrissy Kopple; Christa Merlino; Christie Boutte; Julie Khani; Connie Woodburn; Craig Norman; Dave Sencabaugh; Diane Darvey; Don Bell; Ed Kaleta; Eric Douglas; Eric Juhl; Ghassan Hourani; Gregg Jones; Heather Smith; Heidi Ecker; Isaac Reyes; Jay Bogdan; Jill McCormack; Joe Montoto; Joel Kurzman; Jon McArthur; Josh M. Flum; Joyce Garlington; jrobertson@fredsinc.com; Julie Philp; Karen White; Kathleen Jaeger; Larry Burton; Laura Asbury; Laura Miller; Lauren Rowley; Lis Houchen; Magalie Normil; Marc Schloss; Margaret Nowak; Mary Diggs; Mary Ellen Kleiman; Mary Staples; Maxine Johnson; Melanie Grenier; Michael Mone; Michelle Cope; Mike Ayotte (Michael.Ayotte@CVSCaremark.com); Mike Erlandson; Mike Sargent; Ravi Upadhyay; Rich Mazzoni; Sandra Guckian; Sheree Barton; Steve Anderson; Susan Flack; Susan Giuliano; Tedria Hampton; Tony Unan; Sussman, Wendy

**Subject:** Policy Council Call - DEA Issues - Tuesday May 1 @ 1:15 p.m.

Dear Policy Council:

To follow up from today's call on addressing DEA issues, NACDS will host a Policy Council call Tuesday, May 1 at 1:15 p.m. – 2:00 p.m. EDT. The call in number and pass code are: 1-888-450-5996, and 265044

The NACDS Board of Directors has directed the Policy Council to develop policy solutions to respond to recent DEA actions in which DEA is expecting pharmacists to be enforcement agents with respect to prescriptions for pain medications. Potential solutions for discussion are:

- DEA has discussed with Surescripts the potential to leverage the Surescripts network and use it as an analytics engine for an early warning system for patients who are doctor shopping and prescribers who are writing questionable prescriptions.
- Since the DEA issue is arising out of Florida, develop a plan to require prescribers to access information in the state prescription drug monitoring program before issuing a prescription for pain medication.
- Work with NABP to inter-connect the state prescription drug monitoring programs.
- The current PDUFA draft legislation from the House E&C committee would require DEA to work with FDA to address drug shortages. We could expand this to include "diversion" activities, so that FDA would be in a position to deal with DEA over patient care matters here, too. Since FDA has a patient focus, this could require DEA to consider the impact on patient care their policies would cause. The exiting language in the PDUFA legislation is pasted below:

## **SEC. 506C**

### **(e) COORDINATION WITH ATTORNEY GENERAL.—**

Not later than 30 days after the receipt of a notification described in subsection (a), the Secretary shall— (1) determine whether the notification pertains to a controlled substance subject to a production quota under section 306 of the Controlled Substances Act; and (2) if necessary, as determined by the Secretary— (A) notify the Attorney General that the Secretary has received such a notification; (B) request that the Attorney General increase the aggregate and individual production quotas under section 306 of the Controlled Substances Act applicable to such controlled substance and any ingredient therein to a level the Secretary deems necessary to address a shortage of a controlled substance based on the best available market data; and (C) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide to the Secretary a written response detailing the basis for the Attorney General's determination.

## **SEC. 903. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.**

Section 306 of the Controlled Substances Act is amended by adding at the end the following: (h)(1) Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall— (A) complete review of such request; and (B)(i) as necessary to address a shortage of a controlled substance, increase the

aggregate and individual production quotas under this section applicable to such controlled substance and any ingredient therein to the level requested; or (ii) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide a written response detailing the basis for the Attorney General's determination.

**SEC. 906. ANNUAL REPORT ON DRUG SHORTAGES.**

Not later than 18 months after the date of the enactment of this Act, and annually thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on drug shortages that ...

(3) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

**SEC. 907. ATTORNEY GENERAL REPORT ON DRUG SHORTAGES.**

Not later than 6 months after the date of the enactment of this Act, and annually thereafter, the Attorney General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on the Judiciary of the Senate a report on drug shortages that ...

(2) describes the coordination between the Drug Enforcement Administration and Food and Dug Administration on efforts to prevent or alleviate drug shortages;

**Kevin N. Nicholson, R.Ph., J.D.**

Government Affairs and Public Policy  
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